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### **REMARKS**

Applicants respectfully request that the subject application be preliminarily amended as set forth in the foregoing amendment prior to calculation of the filing fees. Applicants also respectfully request the Examiner to consider the foregoing amended and added claims in the first Office Action on the merits.

The specification was amended to provide a cross-noting to the US patent application the subject continuing application is claiming domestic priority to.

The allowed claims of the corresponding parent application are canceled in the foregoing amendment. Claims 34, 36, 38, 60-62 and 63 were amended in the foregoing amendment so as to more distinctly claim Applicants' invention. Claims 73-99 were added to claim embodiments of the present invention. The above-described amendments to the claims are supported by the disclosure of the originally filed parent application including the originally filed claims.

Included herewith is a marked-up version of the amendments to the subject application by the current amendment. The marked-up versions are found on the pages captioned or entitled "Details of Amendments" that follow the signature page of the within Response.

Applicant: Allan Carl, et al.  
U.S.S.N. 08/UNASSIGNED  
Preliminary Amendment Filed With Application  
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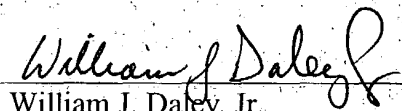
It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Preliminary Amendment. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. 04-1105.

Respectfully submitted,  
Edwards & Angell, LLP

Date: June 20, 2003

By:



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### DETAILS OF AMENDMENTS

Please preliminarily amend the subject continuing application as follows and before calculating the filing fee therefor:

#### IN THE SPECIFICATION

Page 1, delete the Title in its entirety and replace therewith the following:

SYSTEMS, METHODS, DEVICES AND DEVICE KITS FOR FIXATION OF BONES AND SPINAL VERTEBRAE.

Page 1, before line 1 insert the following paragraph:

This application is a continuation of co-pending U.S. application serial number 09/536,732, filed March 28, 2000, now allowed, which application claims the benefit of U.S. Provisional Application Serial No. 60/133,356 filed May 10, 1999, all the teachings of which are incorporated herein by reference in their entirety.

#### IN THE CLAIMS

**Cancel** claims 1-33, 39-59, and 64-72.

**Amend** claims 34, 36, 38, 60-62 and 63 to read as follows:

34. (AMENDED) An implantable spinal fixation system, comprising:

an arcuate implant member of a size sufficient to extend between two adjacent vertebrate, the arcuate implant being sized so as to extend through a preformed aperture in each of the two adjacent vertebrae.

36. (AMENDED) A spinal system comprising:

a mammalian spine with a surgically implanted arcuate member extending between two adjacent vertebrae, the arcuate member being configured so as to extend through a preformed aperture in each of the two adjacent vertebrae.

38. (AMENDED) A spinal fusion kit comprising an arcuate fixation member that is configured so as to extend between two adjacent vertebrae and through a preformed aperture in each of the two adjacent vertebrae.

60. (AMENDED) A method for stabilizing adjacent vertebrae of a spine, comprising:  
providing a cutting device including a rotating cutting implement having a midpoint;  
positioning the cutting device proximal a surface of the adjacent vertebrae and so that the rotating cutting implement midpoint is located between the adjacent vertebrae;

rotatably cutting a common channel in the adjacent vertebrae with the rotary cutting implement; and

inserting a biscuit implant into the common channel so that the implant extends between the adjacent vertebrae and through the intervertebral space, the space between the adjacent vertebrae.

61. (AMENDED) The stabilizing method of claim 60 wherein the cutting device being provided is configured such that the rotating cutting implement is moveable between a first position in which the rotating cutting implement is disposed within the cutting device and a second position in which a portion of the rotating cutting implement extends outside of the cutting device and wherein the step of rotatably cutting includes moving the rotating cutting implement to the second position so as to rotatably cut the common channel in the adjacent vertebrae.

62. (AMENDED) The stabilizing method of claim 60 wherein the biscuit implant includes a spacer element and wherein the step of inserting includes inserting the biscuit implant into the common channel such that the spacer element is disposed in the intervertebral space.

63. (AMENDED) The stabilizing method of claim 60 wherein the step of positioning includes positioning the cutting device so the ~~rotating~~ cutting implement midpoint is located at the midpoint between the adjacent vertebrae

**Add** new claims 73-99 that read as follows:

73. (NEW) The implantable spinal fixation system of claim 34, wherein the preformed aperture in each of the adjacent vertebrae is of a constant radius and wherein the arcuate implant member is configured so as to extend through each constant radius preformed aperture.

74. (NEW) The implantable spinal fixation system of claim 34, wherein the arcuate implant member is configured so as to have a uniform outer diameter.

75. (NEW) The implantable spinal fixation system of claim 34, wherein the arcuate implant member is configured so as to be secured by fixation points within the adjacent vertebrae.

76. (NEW) The implantable spinal fixation system of claim 34, wherein the arcuate implant member is configured and sized so as to be a load bearing member.

77. (NEW) The implantable spinal fixation system of claim 34, further including a plurality of securing mechanisms one for each of the adjacent vertebrae, each securing mechanism being configured so as to secure the securing mechanism to one of the adjacent vertebrae, wherein the arcuate implant member is configured so as to be secured to each of the plurality of securing mechanisms.

78. (NEW) The implantable spinal fixation system of claim 77, wherein each end portion of the arcuate implant member is configured so as to be secured respectively to one of the

plurality of securing mechanisms, thereby securing each end portion to a corresponding one of the adjacent vertebrae.

79. (NEW) The implantable spinal fixation system of claim 34, wherein the arcuate implant member is configured with a plurality of guiding means at each end of the arcuate implant member for guiding an anchor.

80. (NEW) A method for stabilizing adjacent segments of a mammalian bone, comprising implanting an arcuate fixation member so as to extend between the adjacent bone segments vertebrae and through a preformed aperture in each of the adjacent vertebrae.

81. (NEW) The method of claim 80, further comprising the step of localizing opposing portions of the adjacent bone segments proximal to each other before said step of implanting.

82. (NEW) The method of claim 80 wherein the preformed aperture has been drilled in each of the adjacent bone segments.

83. (NEW) The method of claim 80 further comprising the step of forming a through aperture in at least one of the adjacent bone segments.

84. (NEW) The method of claim 83 wherein said step of forming further includes forming a through aperture in each of the adjacent bone segments.

85. (NEW) The method of claim 80 wherein the preformed apertures in each of the adjacent bone segments are formed so as to have a common axis of rotation.

86. (NEW) The method of claim 85 wherein the preformed apertures in each of the adjacent bone segments are formed in the respective bone segment by one of drilling or ablation of the bone by an energy source.

87. (NEW) The method of claim 83 wherein the step of forming includes forming an aperture in at least one of the adjacent bone segments by one of drilling or ablation of the bone by an energy source.

88. (NEW) The method of claim 83 wherein the step of forming includes drilling an aperture in each of the adjacent bone segments so as to create intersecting apertures with convergent paths.

89. (NEW) The method of claim 80, wherein the step of implanting includes successively moving a portion of the arcuate fixation member through the preformed aperture in one adjacent bone segment and into the preformed aperture of the other adjacent bone segment.

90. (NEW) The method of claim 80 wherein the arcuate fixation member is made from one or more of a metal, bone, morphogenic protein, carbon fiber composite, nitinol or a biodegradable material.

91. (NEW) A spinal fixation system, comprising:  
a plurality of securing members, each securing member being configured so as to be secured respectively in one of the adjacent vertebrae;  
an arcuate member of a size sufficient to extend between the two adjacent vertebrae; and  
wherein each of the plurality of securing members is configured so as to mechanically engage separate portions of the arcuate member, thereby securing the arcuate member to each of the adjacent vertebrae.

92. (NEW) The spinal fixation system of claim 91, wherein each of the plurality of securing members are configured so as to be threadably secured respectively in one of the adjacent vertebrae.

93. (NEW) A method for stabilizing adjacent vertebrae of a mammalian spine comprising the steps of:

providing a plurality of securing members, each securing member being configured so as to be secured respectively in one of the adjacent vertebrae and an arcuate member of a size sufficient to extend between the adjacent vertebrae; and

securing one end portion of the arcuate member to one of the plurality of securing members and securing said one of the plurality of securing members to one of the adjacent vertebrae and securing another end portion of the arcuate member to another of the plurality of securing members and securing said another of the plurality of securing members to the other of the adjacent vertebrae.

94. (NEW) The stabilizing method of claim 93, wherein said securing includes threadably secured said each of the plurality of securing members respectively to said one of the adjacent vertebrae.

95. (NEW) A method for stabilizing adjacent vertebrae of a mammalian spine comprising the steps of:

providing an arcuate member of a size sufficient to extend between the two adjacent vertebrae;

rotating the arcuate member from a first position to a second position; and

securing end portions of the arcuate member to respective adjacent vertebrae when the arcuate member is rotated into the second position.



96. (NEW) The stabilizing method of claim 95, wherein said securing includes threadably secured said end portions to said respective adjacent vertebrae.

97. (NEW) The stabilizing method of claim 95, further comprising the steps of:  
localizing a rotating mechanism so a pivot point thereof is disposed at a predetermined location with respect to the adjacent vertebrae;  
securing the arcuate member to the rotating mechanism; and  
wherein said step of rotating includes rotating the arcuate member using the rotating mechanism from the first position to the second position.

98. (NEW) The stabilizing method of claim 97, wherein said securing includes threadably secured said end portions to said respective adjacent vertebrae.

99. (NEW) The stabilizing method of claim 95, wherein:  
said providing includes providing a plurality of securing members; and  
said securing includes:  
    securing one end portion of the arcuate member to one of the plurality of securing members and threadably securing said one of the plurality of securing members to one of the adjacent vertebrae, and  
    securing another end portion of the arcuate member to another of the plurality of securing members and threadably securing said another of the plurality of securing members to the other of the adjacent vertebrae.